

manufacturing quotas and import permits of all other registrants to keep the aggregate production quota within the limits originally established, or, alternatively, the Administrator may reduce the individual manufacturing quota of any registrant whose quota is suspended pursuant to § 1303.24(b) or § 1301.36 of this chapter, or is abandoned pursuant to § 1303.27.

[36 FR 7786, Apr. 24, 1971, as amended at 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13958, Mar. 24, 1997]

#### **§ 1303.27 Abandonment of quota.**

Any manufacturer assigned an individual manufacturing quota for any basic class pursuant to § 1303.23 may at any time abandon his right to manufacture all or any part of such quota by filing with the Drug & Chemical Evaluation Section a written notice of such abandonment, stating the name and Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, of the substance and the amount which he has chosen not to manufacture. The Administrator may, in his discretion, allocate such amount among the other manufacturers in proportion to their respective quotas.

[36 FR 7786, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 46 FR 28841, May 29, 1981; 51 FR 5319, Feb. 13, 1986; 62 FR 13958, Mar. 24, 1997]

### HEARINGS

#### **§ 1303.31 Hearings generally.**

(a) In any case where the Administrator shall hold a hearing regarding the determination of an aggregate production quota pursuant to § 1303.11(c), or regarding the adjustment of an aggregate production quota pursuant to § 1303.13(c), the procedures for such hearing shall be governed generally by the rule making procedures set forth in the Administrative Procedure Act (5 U.S.C. 551-559) and specifically by section 306 of the Act (21 U.S.C. 826), by §§ 1303.32-1303.37, and by the procedures for administrative hearings under the Act set forth in §§ 1316.41-1316.67 of this chapter.

(b) In any case where the Administrator shall hold a hearing regarding

the issuance, adjustment, suspension, or denial of a procurement quota pursuant to § 1303.12, or the issuance, adjustment, suspension, or denial of an individual manufacturing quota pursuant to §§ 1303.21-1303.27, the procedures for such hearing shall be governed generally by the adjudication procedures set forth in the Administrative Procedures Act (5 U.S.C. 551-559) and specifically by section 306 of the Act (21 U.S.C. 826), by §§ 1303.32-1303.37, and by the procedures for administrative hearings under the Act set forth in §§ 1316.41-1316.67 of this chapter.

[36 FR 7786, Apr. 24, 1971, as amended at 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

#### **§ 1303.32 Purpose of hearing.**

(a) The Administrator may, in his sole discretion, hold a hearing for the purpose of receiving factual evidence regarding any one or more issues (to be specified by him) involved in the determination or adjustment of any aggregate production quota.

(b) If requested by a person applying for or holding a procurement quota or an individual manufacturing quota, the Administrator shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the issuance, adjustment, suspension, or denial of such quota to such person, but the Administrator need not hold a hearing on the suspension of a quota pursuant to § 1301.36 of this chapter separate from a hearing on the suspension of registration pursuant to those sections.

(c) Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

[36 FR 7786, Apr. 24, 1971, as amended at 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13958, Mar. 24, 1997]

#### **§ 1303.33 Waiver or modification of rules.**

The Administrator or the presiding officer (with respect to matters pending before him) may modify or waive any rule in this part by notice in advance of the hearing, if he determines

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that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.

[36 FR 7786, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

#### **§ 1303.34 Request for hearing or appearance; waiver.**

(a) Any applicant or registrant who desires a hearing on the issuance, adjustment, suspension, or denial of his procurement and/or individual manufacturing quota shall, within 30 days after the date of receipt of the issuance, adjustment, suspension, or denial of such quota, file with the Administrator a written request for a hearing in the form prescribed in § 1316.47 of this chapter. Any interested person who desires a hearing on the determination of an aggregate production quota shall, within the time prescribed in § 1303.11(c), file with the Administrator a written request for a hearing in the form prescribed in § 1316.47 of this chapter, including in the request a statement of the grounds for a hearing.

(b) Any interested person who desires to participate in a hearing on the determination or adjustment of an aggregate production quota, which hearing is ordered by the Administrator pursuant to § 1303.11(c) or § 1303.13(c) may do so by filing with the Administrator, within 30 days of the date of publication of notice of the hearing in the FEDERAL REGISTER, a written notice of his intention to participate in such hearing in the form prescribed in § 1316.48 of this chapter.

(c) Any person entitled to a hearing or to participate in a hearing pursuant to paragraph (b) of this section, may, within the period permitted for filing a request for a hearing or notice of appearance, file with the Administrator a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

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(d) If any person entitled to a hearing or to participate in a hearing pursuant to paragraph (b) of this section, fails to file a request for a hearing or notice of appearance, or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing or to participate in the hearing, unless he shows good cause for such failure.

(e) If all persons entitled to a hearing or to participate in a hearing waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may cancel the hearing, if scheduled, and issue his final order pursuant to § 1303.37 without a hearing.

[36 FR 7786, Apr. 24, 1971, as amended at 36 FR 18731, Sept. 21, 1971; 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

#### **§ 1303.35 Burden of proof.**

(a) At any hearing regarding the determination or adjustment of an aggregate production quota, each interested person participating in the hearing shall have the burden of proving any propositions of fact or law asserted by him in the hearing.

(b) At any hearing regarding the issuance, adjustment, suspension, or denial of a procurement or individual manufacturing quota, the Administration shall have the burden of proving that the requirements of this part for such issuance, adjustment, suspension, or denial are satisfied.

[36 FR 7786, Apr. 24, 1971, as amended at 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13958, Mar. 24, 1997]

#### **§ 1303.36 Time and place of hearing.**

(a) If any applicant or registrant requests a hearing on the issuance, adjustment, suspension, or denial of his procurement and/or individual manufacturing quota pursuant to § 1303.34, the Administrator shall hold such hearing. Notice of the hearing shall be given to the applicant or registrant of the time and place at least 30 days prior to the hearing, unless the applicant or registrant waives such notice and requests the hearing be held at an